



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,630	11/28/2001	Kimberly A. Gillis	102729-10 (AM 100491)	3476

21125 7590 07/28/2005

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/996,630

Applicant(s)

GILLIS ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 07 July 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): rejection under 35 USC 103(a).

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 18--22, 53-54.

Claim(s) objected to: none.

Claim(s) rejected: 1-17, 51 and 52.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s): _____.

13. ☐ Other: _____.


GARY BENZON, PH.D.
SUPERVISORY/PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 11. does NOT place the application in condition for allowance because: The request for consideration has been fully reviewed and found persuasive in part. With regard to the rejection under 35 USC 112, first paragraph, Applicants argue that the claims 1-17, and 51-52 are enabled and the instant specification clearly discloses the differential expression of KIAA 18 and KIAA 96, which directly correlates with prostate cancer tumor growth as compared to normal tissue. Applicants also argue that the table 1 of the instant specification discloses the correlation of KIAA 18 and KIAA 96 gene expression with tumor grade (1.6 fold and 3.6 fold increase/decrease as compared to normal tissue). The arguments and the table 1 of the specification are thoroughly reviewed and the arguments are found unpersuasive. Examiner notes that the table 1 of the specification discloses increase in KIAA 18 and a decrease in KIAA 96 with the progression of the tumor grade, however, the table 1, does not disclose the number of tumor samples and the number of controls studied and the statistical significance value or probability level of significance. Thus the 1.6 fold or 3.6 fold increase or decrease is not a statistically significant value since the data in table 1 lacks statistical significance. Thus the correlation is not of a statistically significant increase/decrease with the progression of the tumor grade. This data is insufficient to establish the correlation of any one of these markers in assessing the subjects afflicted with prostate cancer.

Applicants also argue that the specification does not rely on the relationship of the two markers, instead the fold change in table 1 indicates the change in the expression level of each marker, compared independently to the expression level of each marker found in normal tissue, and clarify that any one of the markers is required for assessing a subject afflicted with prostate cancer. Applicants' arguments are fully considered and Examiner recognizes that any one of the markers is selected to assess the condition in a subject, however, Examiner notes that the claimed invention is not enabled for assessing a subject afflicted with prostate cancer based on the levels of expression of any one of these markers because the specification fails to provide any statistically significant predictable value of any one of these markers with the progression of the prostate cancer. Further the arguments based on table 1 of the specification are not persuasive as discussed above, since the specification does not provide any statistically significant data to establish the correlation of any one of these markers with the disease progression. Therefore the rejection is maintained herein.

With regard to the rejection made under 35 USC 103(a), Applicants arguments are found persuasive and the rejection is withdrawn herein in view of the persuasive arguments directed towards the absence of motivation to combine the teachings of An et al. in view of Nagase et al.